DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention [30Day-22-21HD]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled the "One Health Surveillance for Zoonotic SARS-CoV-2 Events" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 13, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

One Health Surveillance for Zoonotic SARS-CoV-2 Events - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCEZID seeks OMB approval for One Health Surveillance for Zoonotic SARS-CoV-2 Events through the use of two forms: One Health Case Investigation Form for Animals with SARS-CoV-2, and Zoonotic SARS-CoV-2 Event Form. Description of these forms and activities associated with this study, including burden to respondents can be found below.

Zoonotic SARS-CoV-2 Event Form:

Although it is now well established that SARS-CoV-2 is a zoonotic virus (i.e., can be spread between people and animals), little information exists on the prevalence or likelihood of zoonotic transmission events. Currently, reporting of zoonotic SARS-CoV-2 transmission events is not systematically reported. Without this crucial information, however, interpreting data on SARS-CoV-2 infection in animals, especially the overall contribution of zoonotic transmission to the spread of COVID-19, is incomplete. The information gathered using this surveillance mechanism will provide insight into the role of animals in SARS-CoV-2 transmission and will also provide context for understanding prevalence of linked human and animal infections throughout the nation.

Positive SARS-CoV-2 animal samples must be confirmed by United States Department of Agriculture (USDA) National Veterinary Services Lab (NVSL); however, without the proposed surveillance mechanism, data on linked human and animal transmission events which yield negative results would not be

tracked at the national level. CDC and USDA guidance recommends state-level health authorities, namely state public health veterinarians and state animal health officials, are involved in approving and coordinating animal SARS-CoV-2 testing. These officials are therefore the primary target audience for this surveillance form, in addition to tribal, local and territorial health authorities. The Zoonotic SARS-CoV-2 Event form includes questions intended to improve our understanding of the number of cases state officials are asked to consult upon regarding SARS-CoV-2 testing for potential zoonotic transmission events, the proportion of those events that are tested for SARS-CoV-2, and corresponding relevant epidemiological data (epidemiological links to other cases of SARS-CoV-2 in people or animals, clinical signs, etc.), results, etc. This form will fill a needed gap over the next three years.

In addition to the primary reason for the Zooonotic SARS-CoV-2 Event form, it will also be used to replace paper-based reporting for CDC-funded research. Currently, CDC's One Health Office has funded surveillance and research at sites throughout the nation. This surveillance form will be used to report all linked human and animal testing for SARS-CoV-2 to CDC that is occurring through funded surveillance activities, including the status and circumstances for testing. This will relieve the requirement for less secure reporting such as paper-based reporting forms sent through email.

More broadly, we expect this form may be generalized in the future to encapsulate surveillance for other zoonotic respiratory viruses. This surveillance form therefore offers the opportunity to test and iterate upon surveillance mechanisms prior to the advancement of a broader surveillance system.

One Health Case Investigation Form for Animals with SARS-CoV-2:

Currently, most animal samples that test positive for SARS-CoV-2 are confirmed by USDA NVSL, and are reported to the World Organization for Animal Health (OIE). However, the information collected is largely restricted to information on the animal case, including animal species, number of affected animals, and clinical signs. Richer epidemiological data, including the routes that animals become exposed to SARS-CoV-2 and potential transmission events back to people, are needed to better understand the zoonotic potential of SARS-CoV-2, whether transmission is becoming sustained among animal populations, and the public health risks that infected animals may pose. Through this data collection tool, state and local public health and animal health officials will be able to use a standardized approach to collect epidemiological data while conducting One Health epidemiologic investigations over the tool's expected reporting lifespan of three years.

CDC and USDA guidance recommends state-level health authorities, namely state public health veterinarians and state animal health officials, conduct follow-up investigations if and when an animal is identified as positive for SARS-CoV-2. These

officials, in addition to other state, tribal, local, and territorial (STLT) collaborators conducting research or surveillance within their jurisdiction are therefore an appropriate target audience for this surveillance form. This form involves voluntary reporting from STLT health officials conducting epidemiological investigations to enter case information and return it to CDC. This tool was designed by CDC staff at the request of STLT partners.

These data will be used to describe the transmission dynamics and natural history of SARS-CoV-2 infection.

Specifically, this tool will assist in collecting and compiling data to better understand the zoonotic potential of SARS-CoV-2 from humans or other sources, and the role animals infected with SARS-CoV-2 may play in onward transmission to humans or other animals.

CDC requests approval for an estimated 9,000 annual burden hours for this collection. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of	Form Name	Number of	Number of	Average Burden
Respondents		Respondents	Responses	per Response
			per	(in hours)
			Respondent	
State,	One Health	50	20	1
tribal,	Case			
local, and	Investigation			
territorial	Form for			
health	Animals with			
officials	SARS-CoV-2			
State,	One Health	80	400	15/60
tribal,	Consultation			
local, and	Form			
territorial				

health		
officials		

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